

## **Air Protection Division's Issues for the Pennsylvania Enforcement Meeting**

**August 9, 2018**

### **1) Ethylene Oxide (EtO)**

#### ***Background***

EtO is listed as a hazardous air pollutant in the 1990 Clean Air Act (CAA) Amendments. In December 2016 the U.S. Environmental Protection Agency (EPA) updated its EtO inhalation cancer risk estimate. The prior estimate was based on experimental animal results, while the 2016 estimate relies more on human study data. Formerly categorized as a probable carcinogen, the 2016 update concluded that EtO is carcinogenic to humans, in agreement with the International Agency for Research on Cancer (2012). Human studies show that sufficient exposure to EtO may result in lymphoid cancer and breast cancer in females.

Depending on exposure assumptions, the updated EtO inhalation cancer risk estimate is about 30-60 times higher than prior values. This means EPA now believes EtO is considerably more potent than previously thought for inducing human cancer. Evidence considered in the 2016 update indicates that children under 16 years of age have greater susceptibility to EtO's inhalation cancer risk. The updated EtO cancer potency information supports the need to reduce EtO air emissions.

#### ***Region 3 EtO Pennsylvania facilities with risks greater than 100 in a million\*:***

*B Braun Medical, Inc., Allentown, PA (Commercial sterilizer) Major source—3.3 tons per year (TPY) EtO emissions*

#### ***Region 3 EtO Pennsylvania facilities with risks approximately 50 in a million\*:***

*Oakland VA Medical Center, Pittsburgh, PA (Hospital sterilizer) Minor source—0.002 TPY EtO emissions*

*\*While EtO is the primary risk driver at this location, the total risk includes other air pollutants.*

#### **CAA Compliance Summary – compiled from EPA's ECHO Database:**

- B. Braun Medical, Inc. – Allentown, PA; CAA Major Source. Last CAA On-site inspection from PADEP 3/14/2018, last CAA Off-Site Inspection 6/12/18. EPA ECHO Database does not show any formal enforcement actions within the last five years by either PADEP or EPA. Commercial Sterilizer.
- Oakland VA Medical Center – Pittsburgh, PA – CAA Synthetic Minor Source. Last CAA On-Site Inspection from PADEP 8/25/2016, last CAA Off-site inspection 9/11/14. ECHO Database does not show any formal enforcement actions within the last five years by either PADEP or EPA. Hospital/ Sterilizer

## **2) Control Technology Guidelines Volatile Organic Compounds Reasonable Available Control Technology State Implementation Plan (CTG VOC RACT SIP) Revision**

The Pennsylvania Department of Environmental Protection (PADEP) shared with the EPA Region 3, Air Protection Division (APD) a draft of their CTG VOC RACT SIP revision. APD had several phone calls and exchanged emails over the past several months with PADEP to provide feedback and suggestions on the draft SIP revision. PADEP did not completely address EPA's concerns in their proposed rule. On 7/12/18, EPA and PADEP had a phone call to discuss EPA's outstanding concerns on the proposed CTG RACT SIP. During the call, PADEP agreed to provide additional information to EPA. However, EPA provided written comments on the record on 7/16/18. During this entire process, PADEP did resist the changes and we now know that PADEP was concerned that the level of detail provided and requested was not appropriate for the level of impact of the issues raised. PADEP has requested that EPA staff take a bigger picture view of regulations in the future and be more open to dropping issues that are not critical. APD management has discussed this issue with the PADEP Air Director and we have agreed to raise issues to mid-level and higher level managers as necessary in the future.